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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,994	12/03/2003	Kedar R. Belhe	47563.0015	4512
57600	7590	10/18/2006	EXAMINER	
HOLLAND & HART LLP 60 E. SOUTH TEMPLE SUITE 2000 SALT LAKE CITY, UT 84111			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,994

Applicant(s)

BELHE ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-18 is/are allowed.
- 6) ☒ Claim(s) 1-12, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 1, the configurations of the snare and the suture are uncertain, since they are said to be deployed on or inserted through a vessel opening, where the vessel is an unpatentable part of the human body, which essentially has been claimed as a structural part of the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kammerer (5,562,684). Kammerer discloses, at least in figures 4 and 16-25 and in col. 6, line 60 to col. 7, line 60 and col. 8, line 48 to col. 9, line 55; a closure system usable for a vessel, where the system includes a sheath (52), a snare (74), and a suture (100) with a pre-tied knot (102) on a proximal end, where the snare comprises a V-shaped (at its proximal portion) wire loop with a memory, and where the pre-tied knot forms a slidable knot.

5. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al. (5,129,912). Noda et al. disclose, at least in figures 6-7G, a method of closing a vascular opening utilizing a pre-tied knot, where the method includes providing a suture (18) having a free end portion and pre-tied portion (36), utilizing a suture device (10, 22, or 70) to position the suture or extending a free end portion of the suture through the pre-tied portion, and cinching the pre-tied knot.

Allowable Subject Matter

6. Claims 13-18 are allowed.

7. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method of closing a vascular opening utilizing a vascular closure device, where the method includes, inter alia, inserting a sheath through a vessel opening, inserting a snare into the vessel on a first side of the vessel opening, inserting a suture with a pre-tied knot into a second side of the opening, and directing the distal end of the suture through the pre-tied knot at the proximal end of the suture.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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8. Claims 4, 5, 10, and 11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a vascular closure system including, inter alia, a sheath, a snare, and suture having a pre-tied knot at its proximal end, where the system further includes a handle set with the pre-tied knot of the suture releasably attached to the handle set and a hub with a one-way silicone hub valve.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Goldrath (5,330,488), Dana et al. (6,746,457), and Diduch et al. (2002/0147456) teach devices with sheaths, snares, and sutures.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

October 16, 2006